Study title: Legacy Effects of CALERIE™, a 2-year Calorie Restriction Intervention, on Hallmarks of Healthspan and Aging

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TUFTS MEDICAL CENTER
TUFTS UNIVERSITY
Jean Mayer USDA Human Nutrition Research Center on Aging
Energy Metabolism Team

INFORMED CONSENT TO PARTICIPATE IN RESEARCH

Legacy Effects of CALERIE™, a 2-year Calorie Restriction Intervention, on Hallmarks of Healthspan and Aging

Principal Investigator: Sai Krupa Das, PhD
Co-Investigators: Susan B. Roberts, PhD, and Roger Fielding, PhD
Study team telephone number: (617) 556-3237

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?
We are inviting you to take part in this study because 10 to 15 years ago you participated in the Comprehensive Assessment of Long-term Effects of Reducing Intake of Energy (CALERIE™) study. Only participants from CALERIE are invited to take part in this study.

What should I know about this research study?
1. Someone will explain this research study to you.
2. Please also read all of the following information carefully.
3. Whether or not you take part is up to you.
4. You can choose not to take part.
5. You can decide to take part and later change your mind.
6. Your decision will not be held against you.
7. You can ask all the questions you want before you decide. Do not sign unless you understand the information in this consent form and have had your questions answered to your satisfaction.
8. If you sign this form and decide to take part in this research study, keep a copy of the signed form for your records. It has information, including important names and telephone numbers, that you may wish to refer to.

Why is this research being done?
The purpose of this research is to determine whether 2 years of calorie restriction, or eating fewer calories, has long-term effects on health and aging. Findings from this study may be used to improve our understanding of aging and advance aging research.

How long will the research last and what will I need to do?
You will be asked to complete one on-site study visit and some off-site assessments. At the study visit, you will be asked to complete procedures that will provide information about your general health and wellness. These include body weight and body composition measurements, a physical activity questionnaire, fitness tests, and other tests that measure how well your body uses sugar and how much energy it uses at rest. You also will be asked to provide blood samples and a urine

sample. If you are unable to complete these procedures during a single study visit, you may request to spread them over 2 shorter visits.

In addition, a series of questionnaires may be completed on-site during your study visit or off-site at your convenience. We also will ask you to complete a dietary recall on 3 separate occasions. For each recall, you will report what you ate and drank in the previous 24 hours. Recalls will be completed by telephone at times most convenient to you. Questionnaires and recalls must be completed within 60 days of your study visit. You may request to receive results from your body composition assessment and some blood tests (e.g., lipid profile, blood glucose, hemoglobin A1c).

More detailed information about the study procedures can be found under the **"Procedures to be Followed"** section.

Is there any way being in this study could be bad for me?
The measurements performed in this study are considered minimal to low risk. For example, you may feel uncomfortable when answering questions related to body shape, disordered eating, mood, gender, or sexual function. Fitness tests also may result in discomfort, pain, or other exercise-related symptoms, such as weakness or headache. You may experience some slight discomfort with the blood draw.

More detailed information about the risks of this study can be found under the **"Risks"** section.

Will being in this study help me in any way?
There are no benefits to you from your taking part in this research. We also cannot promise any benefits to others from your taking part in this research. The results of this study may help to determine whether 2 years of calorie restriction benefits aging. Results also may be used to create or improve programs for extending the period of life people spend in good health.

What happens if I do not want to be in this research?
Participation in research is completely voluntary. You can decide to participate or not to participate. Your alternative to participating in this research study is not to participate.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

PURPOSE OF STUDY

This research study, known as the CALERIE Legacy Study, was designed to determine if the 2-year calorie restriction program followed in the CALERIE study benefits the health and aging of CALERIE participants 10 to 15 years later.

Only participants from the CALERIE study are eligible to take part in the CALERIE Legacy Study. However, unlike CALERIE, this is an observational follow-up study. This means that the study serves to "check in," or "follow up," on the health and wellness of CALERIE participants.

Therefore, you will not be assigned to a diet or study group and will only be expected to complete a series of tests, questionnaires, and other procedures that are the same or similar to those in CALERIE.

We will compare results from this legacy study with those from the CALERIE study to determine if and how calorie restriction affects the aging process over the long term. Since CALERIE was one of the first calorie restriction studies in humans, we expect the results of the CALERIE Legacy Study to improve our understanding of aging and advance aging research. Results also may be used to create or improve programs that support healthy aging.

This study will be conducted at three sites: the Jean Mayer USDA Human Nutrition Research Center on Aging at Tufts University (Tufts-HNRCA) in Boston, MA, Pennington Biomedical Research Center in Baton Rouge, LA, and Washington University School of Medicine in St. Louis, MO.

The study is sponsored by the National Institute on Aging.

We expect up to 216 participants will be enrolled in this study across the 3 study sites in order to have as many former CALERIE participants as possible complete the study.

PROCEDURES TO BE FOLLOWED

If you choose to participate in this research study, you will be asked to sign this consent form and complete the procedures listed below. Some procedures, which are marked with an asterisk (*), must be performed while you are fasting. This means that you will complete these procedures after an overnight fast (10 to 12 hours of consuming only water). After completing the fasted procedures, you will be offered a light meal before continuing with the rest of your visit.

1. **Urine collection*: You will provide a urine sample that will undergo laboratory testing for various factors related to aging. Urine will be collected using the clean-catch method, which helps prevent germs from getting into your urine sample. This method involves cleaning the genital area with a sanitizing wipe before urinating into a sample cup. You will be asked to provide at least 7 teaspoons of urine so that it can be used for multiple tests. If you are a woman of childbearing age, some of this urine will be used to test for pregnancy. Results from the pregnancy test will be available within 45 minutes. If the test is positive, your visit will be stopped, and your data and urine sample will be discarded. Providing a urine sample will take 5 minutes or less.**

2. **Body measurements*:** Your height, waist circumference, and hip circumference will be measured. Your weight will be measured while you are wearing a hospital gown. In total, these measurements will take 10 minutes or less.

3. **Vital signs*:** For these measurements, you will be seated in a quiet room or area. After resting for 5 minutes, 2 blood pressure readings will be taken one minute apart. If these blood pressure readings are inconsistent, a third reading will be taken after waiting another minute. Pulse rate and respiration rate may be taken after or in between blood pressure readings using standard measures. Your body temperature will be measured by mouth using a thermometer. In total, these measurements will take about 15 minutes.

4. **Resting metabolic rate*:** Resting metabolic rate is the number of calories burned when you are lying quietly and awake and at rest. To prepare for this test, you will be asked to lie down and rest quietly for about 30 minutes. A transparent plastic canopy, which is connected to a metabolic cart that measures oxygen and carbon dioxide, will be placed over your head for 30 minutes. You will be asked to remain awake and still during the test. In total, the test will take about one hour.

5. **Blood draw*:** You will have blood drawn from a vein in your arm, and the samples will undergo laboratory testing for factors related to health and aging. You will be expected to provide approximately 7 teaspoons of blood during this procedure, which will take about 10 minutes.

6. **Oral glucose tolerance test*:** An oral glucose tolerance test measures your body's response to drinking a sugar-containing beverage. For this test, you will drink 10 ounces of a sugary beverage, and blood will be drawn every 30 minutes for 2 hours. Approximately 5 teaspoons of blood will be drawn. This test will take up to 2 hours and 30 minutes.

7. **Body composition*:** A dual energy x-ray absorptiometry (DXA) scan will be used to measure the amount of bone, muscle, and fat in your body. For this procedure, you will lie on a table in a hospital gown. A scanner that produces x-rays will move slowly above and below your body to take measurements. The scan will take up to 20 minutes.

8. **Stanford 7-day Physical Activity Recall:** A physical activity recall will be completed with a member of the research team. During this recall, you will be asked to report the approximate number of hours you spent sleeping and engaging in physical activity during the previous week. This recall will take up to 20 minutes. If you are unable to complete this recall on-site, it may be completed by phone; you will have up to 60 days after your study visit to complete this recall.

9. **Medical history and medication log:** A research staff member will ask you to share information about your medical history and medications you are currently taking or may have taken since your completion of the CALERIE study.

10. **Cognitive function:** Cognitive function, or brain-based skills, will be measured using the Cambridge Neuropsychological Test Automated Battery (CANTAB). CANTAB includes 6 sections that test different aspects of cognitive function. It will be completed using a touch-screen device and will take up to 60 minutes.

11. **Physical performance battery:** A physical performance battery including 3 tests will be used to measure your physical function: balance, walking speed, and chair stand. These tests will take a total of 20 minutes.

12. **Treadmill test:** A treadmill test will be used to measure your fitness level. During this test, you will be encouraged to exercise as hard as you can, or until you have reached your highest level of effort. In preparation for this test, we will measure your blood pressure and the electrical activity of your heart while you are at rest. This will require that you wear a blood pressure cuff and have electrodes (small, plastic patches that stick to the skin) placed on your body. After this measurement, you will be fitted with a mouthpiece and nose clip. You will be asked to walk on the treadmill, with the speed and/or incline increased, until fatigue, breathlessness, or other symptoms indicated to the study staff, or yourself, that you should stop. Your breathing, blood pressure, and heart activity will be measured throughout the test. This test should take 30 minutes or less, with an active time of 10 to 20 minutes.

13. **Muscle strength:** Muscle strength will be tested by measuring leg strength and hand grip strength. To measure leg strength, you will be seated and positioned on a strength-testing machine, and your body will be secured with straps at the shoulders, waist, thigh, and ankle. You will then be asked to bend and extend your leg against resistance so that measurements can be taken. You will be asked to repeat this process a few times in different positions. Hand grip strength will be measured using a hand-held device. For this measurement, you will sit in a chair with your arms at your sides and the device in one hand. You will squeeze the device as hard as you can. This process will be repeated for a total of 3 measurements with each hand. These tests will take a total of 20 minutes.

    Other assessments are listed below:

14. **24-hour dietary recalls:** You will complete a total of 3 dietary recalls. Each recall will be administered in an interview format by a trained member of our team. During each recall, you will describe all foods consumed in the 24 hours prior to the interview. You will be given a Food Amounts Booklet to help you recall portion sizes. All recalls will be completed off-site by phone. These recalls will occur on 2 weekdays and one weekend day based on your availability. All recalls must be completed within 60 days of your study visit.

15. **Self-administered questionnaires:** You will be asked to complete the following questionnaires without assistance from the research team. Select questionnaires will be completed electronically, while others will be completed by pen and paper. In addition, some questionnaires will be administered on-site, while others may be completed either on- or off-site. To enable off-site completion of a subset of questionnaires, you will be provided with a link to a secure, online portal; you also will be provided with a pre-paid return envelope, which you can use to mail us your hard copy questionnaire packet if you did not complete it prior to your study visit. These questionnaires will take up to 2 hours to complete and must be completed within 60 days of your study visit. The research team

will send you reminders to help you complete all study components within this timeframe.

- Demographics
- Profile of Mood States Second Edition
- Beck Depression Inventory II
- The CALERIE Legacy Diet and Health Questionnaire
- Rand 36-Item Short Form Survey
- Pittsburgh Sleep Quality Index
- 25-Item Connor-Davidson Resilience Scale
- Three-Factor Eating Questionnaire
- Food Cravings Questionnaire (Trait)
- Multiaxial Assessment of Eating Disorder Symptoms
- Body Shape Questionnaire
- Derogatis Interview for Sexual Functioning

In total, your study visit will take about 8 hours. If you need to arrange to complete in-person study assessments over the course of 2 visits, this time commitment will be spread across 2 days. If you choose this option, are a woman of childbearing age, and did not complete the DXA scan or treadmill test during the first visit, you will need to repeat the pregnancy test during the second visit if it occurs more than 72 hours later. After tests that require fasting, you will be provided with a small meal (a light sandwich with tuna, turkey, or cheese, fruit, and a non-caloric/decaffeinated beverage). You also will be offered a snack (granola/cereal bar without nuts and a beverage) prior to discharge.

Participation in this study can be completed in 10 to 60 days based on your availability and convenience. We expect to enroll study participants over 4 years, between 2022 and 2026.

All procedures performed in this study are for research purposes only. You will interact with scientific investigators and research staff, which may include a project manager, research coordinators/assistants, nurses, and dietary assessment staff. All members of the research staff are trained to interact with participants and administer study procedures.

Tufts-HNRCA will keep your contact information on file for future research opportunities. If you do not wish to be contacted for future research studies, please inform the research staff, and they will remove you from the contact list.

Optional Biospecimen Banking:

This study includes biospecimen banking as an optional component. This means that you can choose to provide or not to provide blood and urine samples (i.e., biospecimens) to a biorepository as part of this study. A biorepository is a place where samples are stored (i.e., “banked”) and distributed for use in future research by other investigators. If you choose to provide blood and urine samples for future research, they will be sent to a biorepository chosen by the study sponsor (the National Institute on Aging). Your name or other identifiers will not be linked with any of your samples, including those sent to the biorepository. Instead, a unique code will be used to label your blood and urine samples. This code, known

as your sample identification number (sample ID), cannot readily be traced back to you. Biospecimens will be stored for an indefinite period, until they are used in full.

Blood will be collected by blood draw, and urine will be collected using the clean-catch method. These procedures also will be performed as part of the main study. However, if you participate in this optional study component, you will be asked to provide 19 more teaspoons of blood than you would if you only participated in the main study. You will not need to provide additional urine, but a small portion of the urine you provide for the main study will be sent to the biorepository for future use.

Because the main study and optional study component use the same procedures for sample collection, biospecimen banking does not involve additional physical risks. However, like all activities involving the collection of personal data or samples, biospecimen banking includes possible loss of privacy and confidentiality. The research staff will take all possible measures to guard against loss of privacy and confidentiality. As mentioned, all blood and urine samples will be labeled with coded sample IDs rather than identifiable private information. Therefore, biorepository staff and investigators who request to use your samples for future research will not know that the samples belong to you, and you will not be contacted for any reason by the biorepository or these investigators. In addition, the results of research performed on your banked samples will not be communicated to you, the study physician, or your primary care doctor, or placed in your medical record.

You will not receive any direct benefit from the participation in the biospecimen banking component of this study.

If you choose to participate in this optional study component, we cannot control who requests to use your samples or how your samples will be used. As a result, there is a small possibility that genetic testing may be conducted on banked samples. With genetic testing, there is a low risk that the results of these tests, if accidentally disclosed, could affect your employment or family relationships. However, as described above, we will do everything to protect against loss of privacy and confidentiality. This includes removing all identifiers before sending samples to the biorepository so that researchers who use your samples will not be able to identify you. In addition, the results of research performed on your banked samples, including results of any genetic tests, will not be communicated to you, the study physician, or your primary care doctor, or placed in your medical record.

Your information and biospecimens (both identifiable and de-identified) will not be used to create products or to deliver services.

If you want to participate in biospecimen banking, you will be asked to provide an additional signature at the end of this form. You do not need to participate in biospecimen banking to enroll in the main study. Your decision to participate or not to participate in biospecimen banking does not affect your enrollment in any future research study or your future care or treatment at Tufts Medical Center or Tufts University.

If you consent to biospecimen banking, you may choose to withdraw consent for any reason at any time. Your decision to withdraw consent will be honored and your samples will be destroyed except under the following circumstances: (1) the biorepository has already distributed your samples; (2) your samples have been completely used; or (3) the code to link you to your samples is no longer available. You may withdraw your consent to allow the use of your banked samples at any time by calling Dr. Sai Krupa Das, the Principal Investigator, at (617) 556-3313 or by making your request in writing and sending it to Dr. Das at 711 Washington St, Boston, MA, 02111.

WITHDRAWAL

If you are eligible to participate and decide to be in the study, the Principal Investigator may still choose to stop your participation in this study if she thinks it is in your best medical interest. In addition, you will be withdrawn if you are found to be pregnant after enrollment. (If you are withdrawn due to pregnancy, you will have the option to restart the study 12 months after giving birth if you remain eligible and the study remains open to enrollment.) You can also leave the research at any time, and it will not be held against you. If you refuse to participate in the study or stop being in this study, it will not affect your care or treatment outside this study, payment for your health care, or your health care benefits.

If you withdraw or are withdrawn from the study, any data collected from you before your withdrawal will still be used for the study.

RISKS

The risks for physical, psychological, social, legal, or economic harm are minimal for all study procedures. All research staff have completed the necessary training for conducting research with human subjects and have been trained in performing study procedures. Potential risks for each procedure are outlined below.

1. **Urine collection:** There is no known risk to you in providing a urine sample.

2. **Body measurements:** Measurement of height, weight, waist circumference, or hip circumference may cause mild discomfort. These measurements will be taken in an area with maximum protection of privacy.

3. **Vital signs:** You may experience temporary discomfort during blood pressure measurements due to pressure from the cuff inflating on your arm. There are no known risks associated with pulse rate, respiration rate, or body temperature measurements.

4. **Resting metabolic rate:** Some participants may experience claustrophobia or discomfort due to the canopy placed around their head during this measurement. You may discontinue the measurement if you experience discomfort.

5. **Blood draw:** Placement of the intravenous (IV) catheter, a small, flexible tube used for drawing blood, may cause pain and/or bruising at the needle insertion site. Trained staff

will lessen these risks using techniques to minimize the possibility of an infection. Before undergoing the blood draw, you will be asked to confirm that you have not donated blood within a month of your study visit.

6. **Oral glucose tolerance test:** Although uncommon, the sugary beverage consumed for this test may cause nausea, vomiting, abdominal bloating, or headache. Placement of the IV catheter may cause pain and/or bruising at the needle insertion site. Trained staff will lessen these risks. (Please note that the same IV catheter will be used for the blood draw and this test, so an additional catheter will not need to be placed to complete this test.)

7. **Body composition:** This research study involves exposure to radiation from a full-body dual-energy X-ray absorptiometry (DXA) scan. This radiation exposure is not necessary for your medical care and is for research purposes only. The total amount of radiation that you will receive in this study is about 2.1 mrem, and is approximately equivalent to a uniform whole body exposure of 2.625 days to natural background radiation. This use involves minimal risk and is necessary to obtain the research information desired. If you are a woman of childbearing age, you will undergo a urine pregnancy test at the start of the study. A DXA scan will be performed only if this test is negative. The pregnancy test will prevent risk to the fetus in case of pregnancy.

8. **Cognitive function:** There are no expected risks from completing the CANTAB assessment for cognitive function. If you show signs of mental stress or fatigue from taking the test, you will be given a break.

9. **Physical performance battery:** A potential risk of the physical performance battery is falling, which is prevented or minimized by staff standing next to you throughout the test for support, if needed. You can choose to stop the assessment if you feel unsafe.

10. **Treadmill test:** This procedure involves treadmill exercise to exhaustion. You may find breathing difficult, or perceive that breathing is difficult, due to the mouthpiece and nose clip required for this procedure. In rare cases, you may experience fainting, chest pain, weakness, vomiting, muscle soreness, headache, or other symptoms. In very rare cases, there is risk of a cardiac event or death. These risks are lessened by medical screening before the test, heart activity and blood pressure monitoring during the test, supervision of the test by trained staff, oversight by clinicians who are certified in advanced life support, and easy-to-access emergency supplies. The study physician or designated trained personnel will provide oversight for this assessment and will stop the test if necessary. You also may stop the test if you become ill or uncomfortable. Measuring the electrical activity of your heart before and during the test is safe, noninvasive, and painless and poses no major risks. For these measurements, electrodes will be placed on your body; you may develop a mild rash or skin irritation where the electrodes are placed.

11. **Muscle strength:** You may experience discomfort or pain during or after the leg strength test. These risks are more likely if you have had a prior knee injury, knee surgery, current arthritis, or musculoskeletal injury affecting the knee. Mild muscle soreness may occur several hours after the test. You may choose to perform the leg strength test with one leg

only if you have had an injury to the other leg. There are no known risks associated with the hand grip strength test.

12. **24-hour dietary recalls:** Some participants may experience stress from recalling and reporting details of the food or beverages that they consumed. If you experience high stress during a recall, you will be given a break.

13. **Questionnaires:** You may experience psychological stress from responding to questions about body shape, disordered eating, mood, gender, or sexual function. Most questionnaires are self-administered, so they can be started and stopped at any time. You also may leave a question blank if it makes you uncomfortable. There are no known risks associated with answering questions related to medical history, medication use, or physical activity, which will be completed with a member of the research team.

14. **Optional biospecimen banking component.** Providing extra blood for future unspecified research purposes is an optional part of this study. The main risk to participants who consent to biospecimen banking is unintentional loss of confidentiality and/or privacy. To lessen this risk, no names or other identifiers will be included on labels used for study samples; instead, all samples will be coded with sample IDs. Storage and handling of biospecimens will be conducted by a biorepository chosen by the National Institutes of Health in accordance with their guidelines for Institutional Biosafety Committees.

Collection of identifiable private information. This study will collect information that can identify you, including personal information and data from study-related procedures. The collection of information that identifies you presents the risk of unintentional loss of confidentiality. This risk is lowered by the use of electronic data entry as well as coded study IDs (for labeling data) and coded sample IDs (for labeling samples). In addition, all information collected during this study will be used for research purposes only and will not become part of your medical record or be transferred outside Tufts-HNRCA with any information that can identify you.

RESEARCH-RELATED INJURY

Emergency medical treatment will be given to you if you are hurt or get sick as a direct result of being in this research study. You or your insurance carrier will be required to pay for any such medical care. Any needed medical care is available at the usual cost. All needed facilities, emergency treatment, and professional services are available to you, just as they are to the general public. The institution will not pay for your treatment if you become ill or injured as part of this study.

COSTS

You and/or your insurance provider will not have to pay for exams, tests, and procedures done for research purposes only or that are covered by the study. These include all exams, tests, and procedures outlined in this form.

PAYMENT

You can receive up to $500 for participating in this study. This payment is to compensate you for your time and to cover potential costs associated with study participation (e.g., local travel to and from the study site).

Payment will be issued based on completion of the following sets of study procedures:

- Blood draw for main study and urine sample: $75
- Vitals and resting metabolic rate: $50
- Oral glucose tolerance test: $50
- Cognitive testing (CANTAB): $20
- Body measurements and DXA scan: $30
- All leg and hand grip strength tests: $25
- Treadmill test and physical performance battery: $25
- All questionnaires: $75
- All dietary recalls: $50
- Blood draw for optional biospecimen banking component: $100

While you are expected to complete all study procedures, you will be allowed to opt out of, or skip, any procedure for any reason without withdrawing from the study. If you complete only some procedures, you will receive a prorated stipend, meaning that you will receive payment based on which procedures you completed. You will not receive a stipend if you stop the study before completing any assessments.

Payment will be issued by mail in the form of a check after you complete the study or stop your participation. It may take up to 28 business days to process this check.

You will be considered to receive reimbursement for some study-related costs if you fit the following criteria:

1. You relocated after your participation in the CALERIE study; and
2. Your relocation requires that you travel a considerable distance to and from the study site for assessments (e.g., participation in the study visit requires air travel or overnight stay[s] at a hotel).

If you fit these criteria, costs for travel to and from the study site and up to 2 nights of lodging will be considered for reimbursement of up to $1200. Costs for local travel, parking, or meals, and any other study-related costs, will not be reimbursed. You must receive pre-approval from the Principal Investigator to receive reimbursement. Each case will be considered individually. You may only request reimbursement once, at the end of your study participation. You must make this request in writing and provide relevant receipts proving costs of travel and/or your overnight stay(s).

If your request is approved, you will be reimbursed in the form of a check after your study participation. It may take up to 28 business days to process this check.

Due to federal tax law, you are required to provide us your social security number in order to process your payments. If you receive over $600 from Tufts University Health Sciences in a single calendar year (either in a single study or multiple studies), you will be issued an IRS 1099 form. This may affect your taxes. Only payments for being in research studies will be used to decide if you should receive the IRS form.

PRIVACY AND CONFIDENTIALITY

As mentioned, this study will collect information that can identify you. All information collected during this study will be used for research purposes only and will not become part of your medical record or be transferred outside Tufts-HNRCA with any information that can identify you. To protect the privacy and confidentiality of all participants, the study uses a secure, online central database as well as unique, coded study IDs and sample IDs. This central database, housed at the Duke Clinical Research Institute (Duke University, Durham, NC), is used for electronic data entry, management, and storage. Some of your data from the CALERIE study, such as your assigned study group and location of participation, also will be included in this database for research purposes. No personal identifying information, such as your name, address, or telephone number, will be entered into the central database. Additional study-related information is stored on password-protected devices on a secure network. Any hard copy study forms (e.g., this consent form) are stored in a locked filing cabinet in a private, secure room in the HNRCA, which has around-the-clock security. Only designated staff at Tufts-HNRCA will have access to this room, and only designated member(s) of the research team will have access to the key to this filing cabinet.

If you decide to take part in this research study, your personal information will not be given to anyone unless we receive your permission in writing.

We will make every effort to keep your information private, but it cannot be completely guaranteed. Certain government agencies (Office for Human Research Protections, Department of Health and Human Services), the Institutional Review Board of Tufts Medical Center and Tufts University Health Sciences, and the study sponsor (the National Institute on Aging) may check records that identify you. This might include your research records and the informed consent form that you signed. The records of this study might also be reviewed to make sure all rules and guidelines were followed.

We may publish the results of this research, which will only include averages of data collected from participants. We will keep your name and other identifying information confidential.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research, except if there is a federal, state, or local law that requires

disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings; see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institute on Aging, which is funding this project, or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

To advance science, it is helpful for researchers to share information they get from studying human samples. They do this by putting it into one or more scientific databases, where it is stored along with information from other studies. Researchers can then study the information combined from many studies to learn even more about health and disease.

If you decide to take part in this study, some of your health information will be placed into one or more scientific databases after it has been stripped of identifiers such as name or address, so that it may be used for future research on any topic and shared broadly for research purposes. A researcher who wants to study the information must apply to the database and be approved. Researchers with an approved study may be able to see and use your information, along with that from many other people but will not be able to connect the information to you in any way. We do not expect any direct benefits for you from research resulting in this sharing of your data and information.

You may stop participating in this study and withdraw permission for your individual data, specimens, and health information to be used for additional or future research at any time. If you choose, you may request to have your data destroyed. However, it may not be possible to withdraw or delete materials or data once they have been shared with other researchers.

A description of this clinical study will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

WHOM TO CONTACT

If you have questions, concerns, or complaints, or think the research has hurt you, please contact the research team at (617) 556-3237. If you wish to speak directly with Dr. Das, she can be contacted at (617) 556-3313. The research team is available Monday through Friday 9 AM – 5 PM.

If you have questions about your rights as a research study subject, call the Tufts Medical Center and Tufts University Health Sciences Institutional Review Board (IRB) at (617) 636-7512. The IRB is a group of doctors, nurses, and non-medical people who review human research studies for safety and protection of people who take part in the studies. Federal law requires the IRB to review and approve any research study involving humans. This must be done before the study can begin. The study is also reviewed on a regular basis while it is in progress. This research study has been reviewed and approved by the IRB of Tufts Medical Center and Tufts University Health Sciences.

Documentation of Consent for Main Study

I have been given a copy of this form. I have read it, or it has been read to me. I understand the information and have had my questions answered to my satisfaction. I agree to take part in this study.

I understand that I will be informed of any new findings developed during the course of this research study that may affect my willingness to stay in this research study.

_____ _____ _____
Participant's Signature Date Time

I have fully explained to _____ the nature and purpose of the above-described study and the risks that are involved in its performance. I have answered all questions to the best of my ability.

_____ _____
Date Principal Investigator or Representative's Signature

Documentation of Consent for Optional Biospecimen Banking

I agree to take part in biospecimen banking, an optional component of this study.

_____Yes **_____No** If Yes, please sign and date below.
Initials **Initials**

_____ _____ _____
Participant's Signature Date Time

I have fully explained to _____ the nature and purpose of the optional study component and the risks that are involved in its performance. I have answered all questions to the best of my ability.

_____ _____
Date Principal Investigator or Representative's Signature